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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,124	03/15/2001	Robert Jason Potter	0942.5030001/RWE	4601

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,124

Applicant(s)

POTTER ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-101,103,107,110-112,114-117,119 and 120 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 91-101,103,107,110-112,114-117,119 and 120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/10/05
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 2/9/05
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to an amendment filed December 14, 2004. Claims 91-101, 103, 107 and 110-120 were previously pending. Applicants cancelled claims 113 and 118 and amended claims 91, 103, 112 and 117. Claims 91-101, 103, 107 and 110-112, 114-117, 119 and 120 are pending and will be examined.
2. Applicants' amendments and claim cancellations overcame the following rejections: rejection of claims 91-101, 103, 107 and 110-120 under 35 U.S.C. 112, first paragraph, written description; rejection of claims 112, 113, 117 and 118 under 35 U.S.C. 112, first paragraph, new matter; rejection of claims 111-115 under 35 U.S.C. 112, second paragraph; rejection of claims 91, 92, 94, 96, 98, 100, 107, 111 and 116 under 35 U.S.C. 102(b) as anticipated by Kotewicz et al.; rejection of claims 91, 92, 94, 96, 98, 100, 107, 111, 112, 116 and 117 under 35 U.S.C. 102(b) as anticipated by Hizi et al. as evidenced by Schatz et al; rejection of claims 91, 92, 94, 96, 98 and 100 under 35 U.S.C. 102(b) as anticipated by Georgiadis et al.; provisional double patenting rejection of claims 91, 92, 96 and 107 over claims of copending application No. 10/661,819.
3. The provisional double patenting rejection of claims 91, 100, 107, 110-112, 114, 115, 117 119 and 120 over claims of copending application No. 09/845,157 are rephrased in view of claim amendments in both applications.
4. Applicants amendments necessitated the new grounds for rejection presented in this office action.

Specification

5. The disclosure is objected to because of the following informalities: the newly submitted description of Fig. 8 should include SEQ ID NO for the sequence presented in the figure.

Appropriate correction is required.

Drawings

6. The drawings are objected to because the sequence shown in Figure 8 contains an error of duplication of nucleotides 1379-1438, and, consequently, duplication of amino acid sequence between amino acids 121 and 140. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 91-101, 103, 107 and 110-112, 114-117, 119 and 120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants amended claims 91 and 103 to add a limitation of a polymerase domain of MMLV reverse transcriptase which has an amino acid sequence of SEQ ID NO: 6 in the wild type form. However, the sequence submitted as SEQ ID NO: 6 contains an error of amino acids 121-140 being duplicated. Therefore, amino acids with numbers above 120 are not the ones that Applicants claim, for example, there is no Lys 152, Gln 190, Thr 197 or Phe 309. Therefore, it is not clear what are the metes and bounds of these claims.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 91, 100, 107, 110, 111, 112, 114, 115, 117, 119 and 120 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19, 20, 22, 23, 25, 26, 28 and 29 of copending Application No. 09/845,157. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 19, 20, 22, 23, 25, 26, 28 and 29 of copending Application No. 09/845,157 are species of claims 91, 100, 107, 110, 111, 112, 114, 115, 117, 119 and 120 of the instant application.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the

reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Specifically, claim 91 of the current application is drawn to an MMLV reverse transcriptase comprising a polymerase domain having RNA-dependent DNA polymerase activity and a substitution in the amino acid sequence of the wild type M-MLV polymerase domain within SEQ ID NO: 6, wherein amino acid number 1 of SEQ ID NO: 6 is the threonine following the initial methionine comprising at least one mutation at an amino acid position selected from the group consisting of Tyr64, Arg116, Lys152, Gln190, Thr197 and Phe 309, whereas claim 19 of the 09/845,157 application is drawn to an MMLV reverse transcriptase comprising a polymerase domain having RNA-dependent DNA polymerase activity and a substitution in the amino acid sequence of the wild type M-MLV polymerase domain within (SEQ ID NO 8), wherein amino acid number 1 of SEQ ID NO: 8 is the threonine following the initial methionine, with amino acid substitutions at positions Leu52, His204, Met289, Thr306, Tyr133, Thr197 or Phe309 and possesses reduced RNase H activity, and/or reduced terminal transferase activity and/or increased fidelity.

Therefore, since SEQ ID NO: 8 is identical to SEQ ID NO: 6, claim 19 of the 09/845,157 application is a species of claims 91 and 111 in that it contains an added limitation of reduced RNase H activity, and/or reduced terminal transferase activity and/or increased fidelity.

Further, claim 22 of the 09/845,157 application is a species of claim 100, since it is drawn to a Thr197 being replaced with glutamic acid and claim 23 of the 09/845,157 application is a species of claims 107 and 110, since it is drawn to a Phe 309 being replaced with asparagine. Claims 25, 26 and 28 of the 09/845,157 application are also species of claims 91 and 111, containing added limitations of replacing Tyr64, Arg116, Gln190 and Val223. Claim 29 is a species of claims 112,

114 and 115, 117, 119 and 120, since it contains the limitation of Glu562 being replaced with glutamine and Asp583 being replaced with asparagines.

Therefore, claims 91, 100, 107, 110, 111, 112, 114 115, 117, 119 and 120 of the instant application are generic to claims 19, 20, 22, 23, 25, 26, 28 and 29 of copending Application No. 09/845,157, or, in other words, claims 91, 100, 107, 110, 111, 112, 114 115, 117, 119 and 120 of the instant application are anticipated by claims 19, 20, 22, 23, 25, 26, 28 and 29 of copending Application No. 09/845,157.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. No references were found teaching or suggesting claims 91-101, 103, 107, 110-112, 114-117, 119 and 120, but they are rejected for reasons given above. No claims are allowed.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS
February 23, 2005


JEFFREY FREDMAN
PRIMARY EXAMINER
2/24/05